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BERNHARD SAXE
FOLEY & LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON DC 2007-5109

In re Application of	:
MURDIN et al	:
Serial No.: 09/868,987	: Decision on Petition
Filing Date: 23 December 1999	:
Attorney Docket No. 032931/0253	:

This letter is in response to the Petition filed on 27 July 2003, under 37 CFR 1.144 to review the restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed with 39 original claims under 35 USC 371 as the national stage filing of PCT/CA99/01230, filed 23 December 1999 which claims priority to a number of US provisional applications. On 4 October 2002, the examiner restricted the claims into five groups and then restricted each group into 26 additional groups in view of the nucleic acid sequences SEQ ID Nos. 1-26.

On 4 December 2002, applicants responded with an amendment to claims 1, 2, 8, 9, 18, 19, 21, 27 and 28, and an election of Group II, claims 1-19, 25 and 36, drawn to DNA, host cells, and a method of preventing infection, with traverse. Applicants selected SEQ ID Nos. 1 and 14 for prosecution. Applicants explained that nucleic and amino acid sequence, SEQ ID No. 1 encodes the polypeptide CPN100686 RY-54, a putative 98kDa outer membrane protein, which has SEQ ID No. 14. The response also contained lengthy arguments concerning the restriction between groups and between the sequences.

On 28 February 2003, the examiner acknowledged the election of Group II and DNA having SEQ ID No. 1. The examiner overlooked the election of DNA encoding SEQ ID No. 14. Claims 2, 8-14, 16, 18-19 and 36 were under examination with respect to DNA having SEQ ID No. 1. Claims 1, 3-7, 15, 17 and 25 were improperly withdrawn from consideration as being directed to other non-elected DNA, including DNA encoding SEQ ID No. 14. Claims 20-24, 26-35, 37-39 were withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions. The lengthy traversal was not sufficiently addressed nor considered by the examiner.

Claims 2, 8-14, 18-19 and 36 were rejected under provisionally obviousness-type double patenting. Claim 2 was rejected under 35 USC 101 as being drawn to products of nature. Claims 2, 4-14, 16, 18-19 and 36 were rejected under 35 USC 112, first and second paragraph. Claim 18-19 were rejected under 35 USC 102(b) as being anticipated by probes or primers from various laboratory catalogs.

On 27 June 2003, applicants filed a response and an amendment to claims 2, 8, 9, 10-14, 16, 18-19 and 36 and added new claims 40-41, which have been renumbered by the Office as claims 79 and 80, under Rule 1.126. Applicants also filed this petition.

DISCUSSION

The file record and petition have been reviewed carefully. The petition states that unity of invention exists between all pending claims because Kalman et al is not prior art. In support of this argument, applicants provided Exhibit A, showing when Accession AE 001641 was first seen at NCBI.

Following an extensive review of the various provisional applications from which this application claims priority, Office concedes that Kalman et al cannot be used to demonstrate that the linking technical feature is not a contribution over the prior art.

Moreover, a review of the groupings in the lack of unity determination shows that several groups contain overlapping subject matter. Because the DNA sequence SEQ ID No. 1 encodes amino acid sequence SEQ ID No. 14, it was not proper to have restricted between DNA described in terms of its nucleic acid sequence and DNA described in terms of the protein sequence it encodes.

In order to correct these deficiencies, the previous restriction is now withdrawn and replaced with the restriction requirement set forth below.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1, in accordance with 37 CFR 1.499.

Group I, claims 1- 19, 25, 36, 38(a), 79 and 80 drawn to DNA, vector, host cell, kit and a method of expressing the DNA and a method of preventing infection by administering the DNA.

Group II, claims 20-24, 27-34, 38(b) drawn to polypeptide and a vaccine.

Group III, claims 26, 35 and 38(c) drawn to an antibody.

Group IV, claim 37(a) drawn to a method of detecting Chlamydia infection using nucleic acid.

Group V, claim 37(b) drawn to a method of detecting Chlamydia infection using a peptide.

Group VI, claim 37(c) drawn to a method of detecting Chlamydia infection using an antibody.

Group VII, claim 39 drawn to a method for inducing an immune response using a polypeptide.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special feature technical features for the following reasons:

The technical feature linking groups I-VII appears to be that they are all related to Chlamydia nucleic acids, peptides, antibodies and various methods of using said products. However, Griffais (see the sequence alignment and SEQ ID No. 1 of U.S. Patent No. 6,559,294) discloses a nucleic acid comprising a nucleic acid sequence, which encodes an immunogenic fragment of polypeptide comprising 50 (see the sequence alignment) consecutive amino acids, thus meeting the limitations of claim 2(c). Moreover, Griffais has a filing date of 11/23/98, which is before the filing date of the instant application's oldest provisional application, 60/113,280, filed on 12/23/98. Therefore, the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

Group I, directed to nucleic acid having SEQ ID No. 1 and Group II, directed to protein having SEQ ID No. 14 are not so linked as to under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed nucleic acid and polypeptide share no common structure, no common function and no property. Therefore, where structural identity is required, such as for hybridization or expression of protein, each product appears to perform a different function in that peptides elicit a specific antibody response, nucleotides hybridize to DNA and antibodies bind to a specific binding site on antigen. Furthermore, they do not make a contribution over the prior art, therefore forming a single general inventive concept under Rule 13.1 because Griffais, US Patent No: 6,559,294 discloses a nucleic acid sequence, which encodes an immunogenic fragment of a polypeptide comprising 50 consecutive amino acids. Hence, unity is lacking among nucleic acid and protein.

The special technical feature of Group I is considered to be polynucleotide, which is not required for Groups II, III, V, VI or VII.

The special technical feature of Group II is considered to be polypeptide which is not required for Groups I, III, IV, or VI.

The special technical feature of Group III considered to be antibody that shares no common structure, property and function from Inventions I-II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice. The antibody of Group III is not required for Groups I, II, IV, V or VII.

The technical feature of Groups IV-VII, respectively, is considered to be methods utilizing nucleic acid, peptides, antibodies or polypeptides, products that share no common structure, property and function and methods of using products so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups IV-VII.

Group IV corresponds to the second method of using the product of Group I. Groups V and VII correspond to the first and second methods of using the second product, Group II. Group VI corresponds to a method of using the third product, Group III. 37 CFR 1.475 allows for the grouping of the first method of using and the first method of making with the first product. Additional methods are not required to be grouped with additional products. Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicants' traversal in Paper No. 10 was not sufficiently addressed in the first action on the merits. In the interest of completing the file record, the traversal will be considered here. The traversal was on the ground(s) that unity of invention is present in all the claims, search and examination of the entire application would not be an undue burden. The arguments were found partially persuasive, in as shown in the new grouping presented above.

The restriction requirement between DNA comprising SEQ ID No. 1 and DNA that encodes SEQ ID No. 14 has been withdrawn. Claim 38, directed to a kit comprising DNA, protein or antibody, has been rejoined to the product claims of Groups I, II and III, respectively.

Non-persuasive arguments are addressed and discussed below.

In Part (A) of the traversal, applicants argue that DNA and the polypeptide have the same essential structural element. Applicants state that the polypeptide SEQ.ID.NO: 14 and a nucleic acid encoding it constitute a single inventive concept and points to part (f) (ii) of the PCT Administrative Instructions, which states that "the structural element may be a single component or combination of individual components linked together.

Applicants further state that claims 1-39 are linked by the common generic special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a) and therefore all the claims with respect to SEQ.ID.NO: 1 and 14 should be examined together.

These arguments are not persuasive because the same or corresponding technical feature does not link the DNA and polypeptide since they do not share a common structure or function or property as indicated above in the restriction. The DNA is made of nucleic acids and polypeptide is made of amino acids. Thus, these two products are not linked by the same or corresponding technical feature as defined by PCT Rule 13.2. Moreover, according to PCT Rule 13.2, the expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Specifically, Griffais (US Patent No. 6,559,294) discloses a nucleic acid comprising a nucleic acid sequence, which encodes an immunogenic fragment comprising 50 consecutive amino acids. Since the invention is not a contribution over the prior art, the DNA

and protein do not share a special technical feature and thus do not constitute a single inventive concept.

Applicants also argue in Part (A) that DNA and protein are related as intermediate and final product. To be considered as intermediate and final product, the intermediate is converted to the final product. This is not the situation that occurs during the transcription and translation of DNA to produce RNA and then protein. When the protein is produced, the DNA still exists in the form of DNA. Thus the DNA and protein are related as an intermediate and final product.

With respect to arguments in Part (B), applicants point to Example 17 of the PCT Administrative Instructions, and argue for the joining of DNA and protein groups. If the DNA and protein shared a technical feature (i.e. the broadest DNA claimed all encode the protein, and the broadest protein claimed is encoded by the DNA) and if that technical feature is special (no prior art teaching either the broadest DNA or protein claims) then applicants' arguments would be persuasive. However in view of the breadth of the claims and the prior art cited on the DNA, unity is lacking between the DNA and protein groups.

Concerning Part (C), applicants argue that the protein and antibody are related like a plug and a socket, pointing to Example 8 of the Annex B, PCT Administrative Instructions. This argument is not persuasive, because antibody-antigen binding is not limited to one region of the antigen. Particular antibodies may bind to many different regions of the antigen and those antibodies are not interchangeable, one with another. Antigens comprise many different epitopes, while antibodies are specific for the one epitope to which they bind. A socket, on the other hand, comprises only one site for which a plug may bind. Thus, the antibody-antigen relationship fails to share a one-to-one corresponding technical feature as in Example 8.

Concerning Part (D), applicants are correct that PCT Rules allow for methods of making and using a product to be grouped back with that product, once that product is free of the prior art. However, this grouping is limited to the rejoinder of the first method of making and the first method of use with the first claimed product. See 37 CFR 1.475. If the first product does not make a contribution over the prior art, then the corresponding methods need not be grouped with it, because the linking technical feature would not be not considered special. Because the product is not a contribution over the prior art, the Office is not required to group the first method of use with the first product. However, in the interest of consistency, because the first restriction requirement grouped the first invention with its first method of use (claim 36) and because the Office has already completed an Office action on the method of use, this grouping will be maintained. With regard to the arguments for joining the method of making with the first product, it is noted that methods of producing DNA are claimed. See Rejoinder Notice below for additional information.

Concerning Part (E), in which applicants present arguments directed at the burden of search, it is noted that search burden is not criteria for unity of invention determination.

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because applicants have already elected and received an examination on the nucleic acid molecules, no election is required and Group I, directed to DNA having SEQ ID No. 1 and DNA encoding SEQ ID No. 14, and the method of using the DNA to prevent infection, will be examined.

DECISION

The petition is **GRANTED-IN-PART**. The restriction requirement between DNA comprising SEQ ID No. 1 and DNA that encodes SEQ ID No. 14 has been withdrawn. Claim 38, directed to a kit comprising DNA, protein or antibody, has been rejoined to the product claims of Groups I, II and III, respectively. The method of claim 37 has been divided in three groups, IV, V and VI, drawn to method of detecting using DNA, protein or antibody, respectively.

The application is being sent back to the examiner for consideration of the amendment and response filed 27 June 2003 and prompt completion of a non-final Office action of the elected invention, Claims 1-19, 25, 36, 38(a), 79 and 80, directed to DNA having SEQ ID No. 1 and encoding SEQ ID No. 14.

Any request for reconsideration of this decision must be made by a renewed petition and must be filed within **TWO MONTHS** of the mailing date of this decision in order to be considered timely.

Since no fee is required for filing this petition, a credit of $130.00 shall be made to Deposit Account No. 19-0741.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA, 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 308-7230.

Jasemine C. Chambers

Jasemine Chambers
TC1600 Group Director